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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 563405**

Issued To: **Endomagnetics Ltd**
The Jeffreys Building
Cowley Road
Cambridge
CB4 0WS
United Kingdom

In respect of:

Design and manufacture of:
- transdermal and surgically invasive magnetic sensing devices, associated probes and sterile injectable magnetic nanoparticles as markers, for sentinel lymph node biopsy guidance;
- sterile single use magnetic marker and associated delivery system, for marking a lumpectomy site.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2010-12-13** Date: **2020-12-11** Expiry Date: **2024-05-26**

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Supplementary Information to CE 563405

Issued To:

Endomagnetics Ltd
The Jeffreys Building
Cowley Road
Cambridge
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NBOG code(s)	Device description	Intended Purpose
Class IIa		
MD 1104, MDS 7010	Sentimag	Magnetic material sensor that is designed to detect small amounts of clinically introduced magnetic tracer or marker.
MDS 7008, MD 0204	Magtrace Magnetic Tracer	Magnetic tracer intended and calibrated for use with the Sentimag Injected; sterile single use
Class IIb		
MD 0204	Magseed Magnetic System	Magnetic marker system for localizing a lesion or other tissue abnormality prior to surgical removal Injected; sterile single use

First Issued: **2010-12-13** Date: **2020-12-11** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 563405**

Date: **2020-12-11**

Issued To: **Endomagnetics Ltd**
The Jeffreys Building
Cowley Road
Cambridge
CB4 0WS
United Kingdom

Date	Reference Number	Action
13 December 2010	7536334	First Issue.
22 December 2011	7765624	Change of scope: Scope was 'Manufacture of magnetic sensing devices and associated probes'. Change of company address: Address was '21 Albermarle Street, London W1S 4BS, UK'. Addition of 'Patheon UK Ltd' as a significant subcontractor for sterile manufacture.
28 November 2012	7912231	Upgrade of certificate to an Annex II Section 3.2. Change of scope: Scope was 'Manufacture of magnetic sensing devices, associated probes and sterile magnetic markers'. Change of company address: Address was '25 Cambridge Science Park, Milton Road, Cambridge CB4 0EY, UK'. Addition of 'Nova Laboratories Ltd' as significant subcontractor for sterile manufacture. Removal of 'Patheon UK Ltd' from the list of subcontractors.
19 February 2015	8287341	Change of company address from: 325 Cambridge Science Park Milton Road, Cambridge, CB4 0WG, United Kingdom. To: The Jeffreys Building, Cowley Road, Cambridge, CB4 0WS, United Kingdom.
26 October 2015	8374118	Certificate Renewal.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 563405**
Date: **2020-12-11**
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The Jeffreys Building
Cowley Road
Cambridge
CB4 0WS
United Kingdom

Date	Reference Number	Action
30 November 2016	8645074	Amendment of scope to indicate the nature of the devices and their intended purpose.
03 May 2017	8734142	Extension to scope to add the sterile single use magnetic marker and associated delivery system, for marking a lumpectomy site. Addition of significant subcontractor Theragenics Corporation, Georgia, USA for Sterile manufacture.
05 February 2019	7780348	Traceable to NB 0086. Administrative Sub Contractor service wording update from Sterile Manufacture to Aseptic Processing for Nova Laboratories and Sterile Manufacture to ETO Sterilisation for Theragenics Corporation.
04 February 2020	3086155	Addition of product table. Addition of subcontractor XL Precision Technologies Ltd, 79 Sadler Forster Way, Teesside Industrial Estate Stockton on Tees, TS17 9JY, United Kingdom.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 563405**
Date: **2020-12-11**
Issued To: **Endomagnetics Ltd**
The Jeffreys Building
Cowley Road
Cambridge
CB4 0WS
United Kingdom

Date	Reference Number	Action
11 December 2020	3265621	Certificate Renewal. Addition of Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, The Netherlands as EU Authorised Representative. Product table updates: - corrected typo 'SentiMag' changed to 'Sentimag', deleted registered symbol from Magseed.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
11 February 2022	3615594	Amended – Change of manufacturer address from The Jeffreys Building Cowley Road, Cambridge CB4 0WS United Kingdom to 330 Cambridge Science Park, Milton Road, Cambridge, CB4 0WN United Kingdom
21 November 2023	30026583	Amended – Change of EU Authorised Representative address to Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands.

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11 February 2022

Endomagnetics Ltd
330 Cambridge Science Park,
Milton Road,
Cambridge,
CB4 0WN
United Kingdom

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 563405	93/42/EEC Annex II excluding Section 4	3615594	Amended – Change of manufacturer address from The Jeffreys Building Cowley Road, Cambridge CB4 0WS United Kingdom to 330 Cambridge Science Park, Milton Road, Cambridge, CB4 0WN United Kingdom

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack

Gary Slack
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
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John M. Keynesplein 9
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21 November 2023

Endomagnetics Ltd
330 Cambridge Science Park
Milton Road
Cambridge
CB4 0WS
United Kingdom

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 563405	93/42/EEC Annex II excluding Section 4	30026583	Change of EU Authorised Representative address to Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
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Endomagnetics Ltd
330 Cambridge Science Park
Milton Road
Cambridge
CB4 0WN
United Kingdom

06 March 2024

Notified Body Confirmation Letter
Reference: EU2023-607/[802812]

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Endomagnetics Ltd
330 Cambridge Science Park
Milton Road
Cambridge
CB4 0WN
United Kingdom
SRN Number: GB-MF-000007233

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sentimag, 506039121SentimagDK	Class IIa	N/A	CE 563405; NB2797
Magseed, 506039121MagseedA7	Class IIb implantable non-WET	N/A	CE 563405; NB2797
Magtrace, 506039121Magtrace57	Class III	N/A	CE 563405; NB2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2024/03/06	Initial issue